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.03 Successfully Reducina Severe Asthma **Exacerbations and Improving Asthma Control** in a Pragmatic Study in African American/ Black (AA/B) and Hispanic/Latinx (H/L) with Patients Moderate-Severe Asthma (PREPARE)



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RATIONALE: Efforts to reduce the disproportionate asthma morbidity in African American/Black (AA/B) and Hispanic/Latinx (H/L) patients have been mostly unsuccessful. In a pragmatic, randomized study, we tested a Patient-Activated Reliever-Triggered Inhaled Corticosteroid (ICS) Strategy (PARTICS) in 1201 AA/B and H/L patients with moderate-to-severe asthma.

METHODS: PREPARE compared the addition of PARTICS [concomitant use of study-provided ICS (beclomethasone dipropionate 80 mcg) with reliever] to usual care (UC) (PARTICS+UC) with UC in 603 AA/B and 598 H/L adults (18-75 years old) who had an Asthma Control Test (ACT) <20 or an exacerbation in the past year (NCT02995733). UC continued at physician discretion. The primary endpoint was verified severe asthma exacerbations. Patients had one instructional visit followed by 15 monthly questionnaires.

RESULTS: PARTICS+UC reduced severe asthma exacerbations by 15.4% (p=0.048) which corresponded to a reduction of 13 exacerbations/100 patient-years. PARTICS+UC improved ACT scores by 3.37 vs. 2.53 points from baseline (p<0.0001). ACT scores improved by ≥3 points from baseline during 11.8% more study months for patients assigned to PARTICS+UC versus UC (p=0.006). Asthma Symptom Utility Index (ASUI) scores improved by 0.12 versus 0.08 points (p<0.0001). The annualized rate of days missed of work/school/usual activities was reduced by 3.33 days/year (p=0.013). The total additional ICS use in PARTICS+UC was 1.3 refills/year.

CONCLUSIONS: A patient-centered, one-time instruction in PARTICS, resulting in minimal additional ICS use, substantially reduces asthma exacerbations and improves asthma control and quality of life in AA/B and H/L adults with poorly controlled asthma.

Anaphylaxis After COVID-19 Vaccination: A **Registry-Based Study**



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RATIONALE: As multiple COVID-19 vaccine doses are needed, it is imperative to understand anaphylactic reactions to COVID-19 vaccines which may preclude complete vaccination. Evidence-based information about vaccine reactions combats vaccine hesitancy.

CONCLUSIONS: 68 cases consistent with anaphylaxis comprised 15% of reactions reported in the COVID-19 Vaccine Allergy Case Registry. Anaphylactic reactions occurred most frequently with Pfizer-BioNtech and first doses in female and White patients. Many occurred in those with prior atopic disease or anaphylaxis. Most reactions required emergency treatment, but hospitalization was rare and no intensive care unit treatment or deaths were reported.

RESULTS: Of 455 patients representing 44 US states, 68 patients (µ age 42 [SD 18] years, 88% female, 82% White, 7% Black, 3% Asian) had reactions considered potentially anaphylactic from Pfizer-BioNTech (n=48, 73%), Moderna (n=17, 26%), and J&J/Janssen (n=1, 1%); 55(81%) occurred with the initial dose. Many patients had a history of atopic disease (n=38, 56%) and anaphylaxis (n=28, 42%), including to medication (n=12, 18%), food (n=11, 16%), venom (n=4, 6%), and idiopathic (n=2, 3%). Anaphylactic reactions involved the respiratory tract (n=46, 68%) and skin/mucosa (n=43, 63%), less commonly the cardiovascular (n=19, 28%) and gastrointestinal (n=5, 7%) systems. Reaction treatment required the emergency department (n=42, 62%) but rarely hospitalization (n=3, 4%); epinephrine intramuscular injection (n=29, 43%) and drip (n=2, 3%) were administered.

METHODS: The COVID-19 Vaccine Allergy Case Registry is an allergist-led effort to collect and share reports of COVID-19 vaccine reactions. Patient and reaction characteristics were summarized for reactions reported as potentially anaphylactic (February 13, 2021 to October 22, 2021).